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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,542	08/25/2006	Mark G. Bock	21654P	9778
210	7590	04/27/2009	EXAMINER	
MERCK AND CO., INC			MCDOWELL, BRIAN E	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	
			1624	
			MAIL DATE	
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			04/27/2009	
			PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,542	<b>Applicant(s)</b> BOCK ET AL.	
	<b>Examiner</b> BRIAN MCDOWELL	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/6/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8 and 9 is/are rejected.
- 7) ☒ Claim(s) 4 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

/BEM/

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-9 are pending in the instant application.

### ***Status of Specification***

Applicant's amendment of the abstract, see Remarks, filed 4/6/2009, with respect to the objection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the objection has been overcome.

### ***Status of Claim Objections***

**The objection of claim 1 is still maintained.**

Applicant's amendment of claim 1 see Remarks, filed 4/6/2009, with respect to the objection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered but is not found persuasive. The examiner currently does not see any amendment to claim 1 (see page 1, line 13, next to last line on page), therefore the objection is maintained. It currently reads "and (5) heterocycle...". Instead, it should read "and (4) heterocycle...". Appropriate correction is required.

***Status of Rejections***

***35 USC § 112 (2<sup>nd</sup> Paragraph)***

Applicant's amendment of claim 8 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the rejection has been overcome.

***Double Patenting***

Applicant's filing of the appropriate terminal disclaimer (in reference to the double patenting rejection of claims 1-9) see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the rejection has been overcome.

***35 USC § 103***

**The 103 rejection is still maintained.**

Applicant's arguments of claims 1-3, 5, 6, 8, and 9 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, have been fully considered but are not found persuasive.

Applicant is reminded on how to obviate this rejection:

*(3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104*

Therefore, the appropriate oath or declaration is needed to obviate this rejection.

**35 USC § 112 (1<sup>st</sup> Paragraph)**

**The 112 rejection is still maintained.**

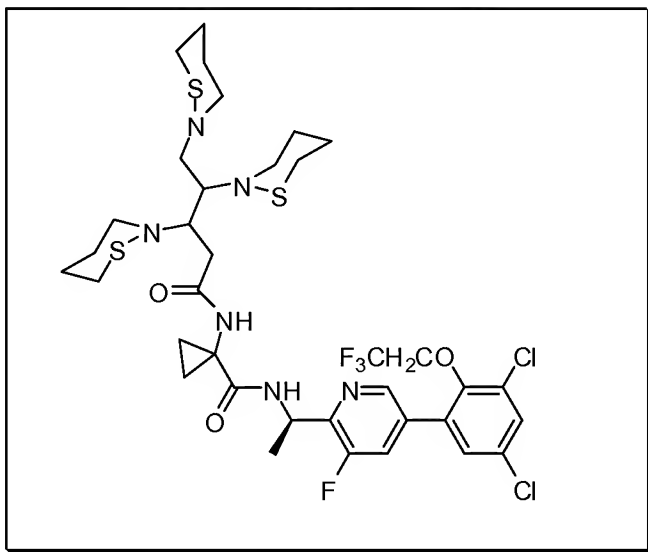
Applicant's arguments of claims 1, 2, and 9 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, have been fully considered but are not found persuasive.

Again, as mentioned in the previous office action, applicant has provided sufficient support for how to make and use compounds where R<sup>4</sup> is unsubstituted or substituted C<sub>1-6</sub> alkyl, wherein the groups in which said alkyl may be substituted with include halogen, nitro, cyano, and SO<sub>2</sub>R<sup>d</sup>

The specification gives some *in vitro* test results on Bradykinin inhibitory effects of a limited number of preferable compounds, however it is too homogeneous to provide a clear evaluation of which moieties attached to the alkyl group out of the many claimed might affect potency to a large or small degree. The pharmaceutical art is unpredictable and target compounds need to be individually assessed for viability. Extremely broad generalizations as found in the instant claims are in contradiction with the basis of quantitative structure-activity-relationship (QSAR).

For example, applicant says that C<sub>1-6</sub> alkyl can be substituted with NR<sup>b</sup>R<sup>c</sup>, wherein R<sup>b</sup>R<sup>c</sup> may form a heterocyclic ring. The following compound may fall within the scope of claims 1, 2, and 9 then:

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Has applicant shown one of ordinary skill in the art how to make and subsequently use this compound as a Bradykinin inhibitor? If so, applicant may be entitled to other substituents.

### **Conclusion**

No claims are allowed.

Claims 4 and 7 are objected to as being dependent upon a rejected or objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Potential Reasons for Allowance**

Claims 4 and 7 embrace novel compounds wherein  $R^4$  is a 6-membered heteroaryl ring or a substituted isoxazolyl group.

The limitations listed supra represent the limitations that are not taught or fairly suggested by the prior art. The closest prior art is by Kuduk *et al.* (WO 2004/019868).

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. M./

Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**